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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/448,692 | 11/24/99 | ASHMAN | A 1527/0E847-U |

| EXAMINER | |
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| KOH, C | |
| ART UNIT | PAPER NUMBER |
| 3738 | 3 |

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DARBY AND DARBY PC
805 THIRD AVENUE
NEW YORK NY 10022

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/448,692 | Ashman |
| **Examiner** | **Group Art Unit** |
| Choon P. Koh | 3738 |

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-49* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-49* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Claim Rejections - 35 U.S.C. § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-17, 20 and 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 13 and 36 recite the limitation "said outer coating" in line 3. There is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 U.S.C. § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this § made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 13-17, 21, 28-31, 35-36 and 38-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruins et al (U.S. Patent No. 4,547,327).

6. With respect to claims 1-4, 28-30 and 35, Bruins et al ('327) teaches a porous implantable prosthesis which comprises polymeric particles having intraparticulate pores, i.e. interstices therebetween, said pores having dimensions effective to permit soft tissue, e.g. 125 to 210 microns, which meets the limitation set forth in claim 2 and overlaps the pore size range of 50 to 200 microns as set forth in claims 3 and 29 (col. 6, lines 48-53).

7. With respect to claims 13-17, 36 and 38-41, Bruins et al ('327) teaches the particles formed of the polymeric inner core and the outer hydrophilic coating of the type claimed (col. 5, lines 48-36; col. 6, lines 12-43).

8. With respect to claims 5 and 31, Bruins et al ('327) teaches the pore volume of between 20-40 percent which falls within the limitation of zero to 60% set forth in the claims (col. 7, lines 56-60).

***Claim Rejections - 35 U.S.C. § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in § 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 6-8 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruins et al (U.S. Patent No. 4,547,327).

11. With respect to pore sizes and pore volume, i.e. the porosity in terms of the percent of pores in the implant material, while Bruins et al ('327) teaches that the size of the pores may be controlled by the size of the particles used and that lower percentage porosity will not allow adequate infusion of body fluids necessary for tissue ingrowth, and higher percentages of porosity will decrease the strength of the implant (col. 6, lines 44-45; col. 7, lines 56-63), the reference does not teach specific pore sizes as set forth in claims 7-8 and 33-34 or specific porosity between about 40 and about 60 percent as set forth in claims 6 and 32.

12. Based on general teaching of Bruins et al above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the polymeric particles having the particle sizes that provide the intraparticulate pores having dimensions effective to permit various type of tissues to grow therein, including soft tissue and also optimize the pore volume to obtain the implant material having desired implant strength and tissue ingrowth for its intended use, e.g. for a soft tissue as claimed.

13. Claims 9-12, 18-19, 22-27 and 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruins et al (U.S. Patent No. 4,547,327) as applied to claims 1 and 21 above, and further in view of Wallace et al (U.S. Patent No. 5,352,715).

14. With respect claims 9-12, 22-27 and 42-49, while Bruins et al ('327) teaches the invention substantially as claimed, the reference does not teach that their polymeric particles are provided in combination with a matrix material, e.g. collagen or injectable collagen, or specific volume of the collagen matrix in the implant material or that the polymeric particles further include a bioactive substance as variously set forth in the claims.

15. With respect to 9-12, 18-19, 22-27 and 42-49, Wallace et al ('715) teaches the benefit of providing a particulate implant material having the particle size in the range of 50 - 250 microns, in collagen, e.g. in the amount of 1-20%, where the implant material is formulated for injection intradermally or subcutaneously to augment soft tissue, e.g. sphincters, to repair tissue defects, to correct congenital anomalies, to correct cosmetic defects, etc. (Abstract; col. 8, lines 21-36; col. 7, lines 7-14).

16. With respect to the particle sizes, Wallace et al teaches that particles larger than 250 microns will generally interfere with injectability of the compositions, while particles below 50 microns will be subject to phagocytosis when administered to soft tissue sites (col. 4, lines 45-54).

17. With respect to claims 10-11 and 43-44, even though Wallace et al (''715) does not teach collagen in specific percentage of between about 30% and about 65% or about 50% as set forth in the claims, Wallace does teach that the persistence and texture of the implant composition can be controlled by adjusting the weight ratio of the particulate material to collagen, with higher amounts of the particulate material corresponding to firmer, more persistent implants.

18. With respect to claims 18-19 and 48-49, Wallace et al also teaches including a bioactive substance in the implant material (col. 7, lines 59-63).

19. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the polymeric particles taught by Bruins et al in combination with optimum volume of collagen taught by Wallace et al ('715) to obtain a soft tissue implant material having the viscosity that is suitable for injection as well as to provide for a desired consistency or firmness in the implant for various intended use, including those set forth in claims 24-26.

20. With respect to claim 27, even though Wallace does not explicitly teach specific amount of implant material to be injected, it would vary with the size of defective site to be repaired or augmented.

21. Claims 20 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruins et al (U.S. Patent No. 4,547,327) as applied to claims 13 and 36 above, and further in view of Chesterfield et al (U.S. Patent No. 5,366,756).

22. With respect to claims 20 and 37, while Bruins et al ('327) teaches the invention substantially as claimed, Bruins et al ('327) does not teach the polymeric particles of one type, e.g. PMMA, coated with another hydrophilic polymeric material, e.g. PHEMA, which further includes a coating of calcium hydroxide over the hydrophilic polymeric coating.

23. Chesterfield et al ('756) teaches the benefit of providing the polymeric particles of implant material with a coating of a tissue ingrowth promotor such as calcium hydroxide and/or a hydrophilic polymeric material (col. 2, line 66 - col. 3, line 13).

24. Chesterfield et al ('756) also teaches that the polymeric particles can carry or incorporate various bioactive substances (col. 3, lines 14-56).

25. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the tissue ingrowth promoting coating taught by Chesterfield et al in implant material taught by Bruins et al to provide the implant material for soft tissue with similar benefits of tissue ingrowth to promote soft tissue repair and augmentation in desired tissue repair site.

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hubbard (5,922,025) teaches soft tissue augmentation material comprising a matrix of particles of a biocompatible ceramic material suitable for soft tissue augmentation, e.g. sphincter augmentation, which can be injected intradermally or subcutaneously.

Manhart (4,375,968) teaches therapeutic calcium hydroxide dental preparation.

Ramp et al (5,968,999) teaches PMMA bone cement composition that includes calcium hydroxide.

Wallace et al (4,803,075) teaches injectable aqueous suspensions of biomaterials, such as collagen, that contain a biocompatible fluid lubricant for improved intrusion of the suspension into soft tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ms. Choon P. Koh whose telephone number is (703) 305-1232. The examiner can normally be reached on Monday - Thursday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Friday from 6:30 AM to 3:00 PM .

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 (formal) and (703) 308-2708 (informal) .

**Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Larry Schwartz of TC3700, Customer Service, whose telephone number is (703) 306-5648.**

Choon P. Koh

Choon P. Koh
April 19, 2001

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700